MAR - 5 2010

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

**Submitter:** Biomet Trauma (aka EBI, LLC)
100 Interpace Parkway
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**Establishment Registration Number:** 2242816

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**Date Prepared:** March 4, 2010

**Trade/Proprietary Name:** OptiLock® VL Distal Radius Plating System

**Common/Usual Name:** Plates/Screws

**Classification Name:** Single/multiple metallic bone fixation appliances and accessories (21 CFR 888.3030)
Screw, fixation, bone (21 CFR 888.3040)

**Device Panel/Product Code:** Orthopedics HRS/HWC

**Device Description:**
The OptiLock® VL Distal Radius Plating System is comprised of a series of anatomically contoured plates, and locking, variable angle locking and non-locking screws, as well as locking pegs intended to be used in the distal radius, ulna (and other small bones). This system may also be used in osteopenic bone. The plates are available in several styles to address the anatomy of the distal radius/ulna. The screws are available in two diameters, in

locking, non-locking and variable angle locking styles. Locking pegs are also available as an option for stabilizing the plate to the bone.

The plates and screws of the OptiLock® VL Distal Radius Plating System are fabricated from titanium alloy (Ti-6Al-4V), which conforms to ASTM specification F-136, or stainless steel alloy which conforms to ASTM specification F-138 or F-139. Plates and screws fabricated from titanium alloy are anodized to color-code the different sizes to assist the surgeon with size selection.

**Indications for Use:**
The OptiLock® VL Distal Radius Plating System consists of a series of plates, screws and locking pegs that are intended for the fixation of intra-articular and extra-articular fractures involving the distal radius, ulna (and other small bones). This system is also intended for use in osteopenic bone. Specific indications include:

1. Fixation of intra-articular and extra-articular fractures
2. Treatment of mal-unions
3. Treatment of non-unions
4. Osteotomies
5. Wrist arthrodesis

**Summary of Technologies**:
The technological characteristics of the OptiLock® VL Distal Radius Plating System are the same, or similar to, other legally marketed predicate devices.

**Substantial Equivalence**:
The OptiLock® VL Distal Radius Plating System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and does not present any new issues of safety or effectiveness. Examples of predicates include: OptiLock® UE Plating System (K062494); EBI Distal Radius Plating System (K040908); IQL Basic Fragment Plate Set (K020221); Synthes Distal Radius Plating Systems (K011335, K071184 and K083694) and Stryker VariAx Distal Radius System (K050512 and K060514). Based upon the engineering analysis, the OptiLock® VL Distal Radius Plating System is substantially equivalent for its intended use to other legally marketed plate and screw systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR ~ 5 2010

Biomet Trauma (AKA EBI, LLC)
% Ms. Margaret Crowe
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K093761
Trade/Device Name: OptiLock® VL Distal Radius Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 24, 2010
Received: February 25, 2010

Dear Ms. Crowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K093761

Device Name: The OptiLock® VL Distal Radius Plating System consists of a series of plates and screws that are intended for the fixation of intra-articular and extra-articular fractures involving the distal radius, ulna (and other small bones). This system is also intended for use in osteopenic bone. Specific indications include:

1. Fixation of intra-articular and extra-articular fractures
2. Treatment of mal-unions
3. Treatment of non-unions
4. Osteotomies
5. Wrist arthrodesis

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Temperature

for mxn

**(Division Sign-Off)**
**Division of Surgical, Orthopedic, and Restorative Devices**

**510(k) Number** K093761